

REMARKS

As a preliminary matter, it is not clear from the May 29, 2007 Notice if the Examiner entered the Amendments listed in Applicants' Response to Notice of Non-Compliant Amendment filed on July 26, 2006 (the "July 26, 2006 Response"), which was responsive to a Notice of Non-Compliant Amendment mailed on July 19, 2006 (the "July 19, 2006 Notice"). Therefore, Applicants have resubmitted the same listing of claims that was filed by Applicants in the July 26, 2007 Response. However, the arguments submitted by Applicants in the July 26, 2006 Response have been revised herein to more distinctly distinguish the claims of the subject application from the cited references.

Claims 1-78 were pending in the subject application. Applicants have canceled claims 2-6, 12-15, 18-19 and 29-78 without prejudice; and amended claims 1, 7, 9, 16, 20, 23 and 26. Claims 1, 7, 9-11, 16-17 and 20-28 are now pending in the subject application.

Claim 1 has been amended to specify that the claimed powder for oral suspension comprises an azithromycin form conversion enhancer. Support for the amendment to claim 1 can be found in the original specification at, for example, page 3, lines 18-22, page 19, lines 20-24, and in the original claim 8.

Claims 7, 9, 16, 20, 23 and 26 have been amended to correct informalities and change claim dependency.

No new matter has been added. Entry of this Amendment and reconsideration of the application are respectfully requested.

Applicants also wish to thank Examiner Lamm for the courtesy of an April 3, 2006 telephonic interview with Applicants' Attorney Lance Y. Liu (Registry No. 45,379). As a result of the interview, it was agreed that claim 1 would be amended to recite "an azithromycin form conversion enhancer" and the Examiner would reconsider the oral suspension recited in amended claim 1 based on the enhanced stability provided by the azithromycin form conversion enhancer.

I. Objection to Claims 20, 23 and 26

The Examiner objected to claims 20, 23 and 26 as allegedly being in improper form.

Applicants have amended claims 20, 23 and 26 to be dependent only upon claim 1. Applicants respectfully submit that the amendments to claims 20, 23 and 26 have fully addressed the Examiner's objection to these claims, and request that the objection be withdrawn.

II. Obviousness-Type Double Patenting Rejections of Claims 1, 7-11 and 16-28

The Examiner has rejected claims 1, 7-11 and 16-28 on the grounds of nonstatutory obviousness-type double patenting as allegedly being unpatentable over claims 1-2 of U.S. Patent No. 6,861,413 ("the '413 patent"). The Examiner has provisionally rejected claims 1, 7-10, 16-20, 23 and 26 on the ground of nonstatutory obviousness-type double patenting as allegedly being unpatentable over claims 1, 3 and 4 of co-pending Application No. 10/355,575 ("the '575 application"). The Examiner has provisionally rejected claims 1, 7-10, 16-20, 23 and 26 on the ground of nonstatutory obviousness-type double patenting as allegedly being unpatentable over claims 15-37 of co-pending Application No. 10/327,383 ("the '383 application").

Applicants previously submitted arguments explaining why the claims of the subject application are patentably distinct from the '413 patent, the '575 application, and the '383 application. (See the July 26, 2006 Response and Applicants' Amendment in Response to Office Action filed on May 4, 2006.) After further consideration, Applicants wish to withdraw these comments. Instead, Applicants will address the obviousness-type double patenting issues once the claims of the subject application are otherwise in condition for allowance.

III. Rejection of Claims 1, 7-10 and 16-19 under 35 U.S.C. § 102(b)

Claims 1, 7-10 and 16-19 have been rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by EP679,400 ("Curatolo") for the reasons set forth in the office action. Applicants respectfully traverse.

Curatolo relates to a method of oral administration of azithromycin which does not exhibit an adverse food effect. Curatolo describes a powder used to make a suspension which "may also contain optional ingredients such as" wetting agents, anti-foaming agents, sweeteners and a buffer (see page 7, lines 2-5 of Curatolo). However, Curatolo does not disclose any powders for oral suspension comprising an azithromycin form conversion enhancer as recited in amended claim 1 of the subject application.

"A claim is anticipated only if each and every element as set forth in the claims is found, either expressly or inherently described, in a single prior art reference." MPEP § 2131 (quoting *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987)).

Curatolo does not disclose any formulation containing an azithromycin form conversion enhancer, let alone an oral suspension comprising a non-dihydrate azithromycin, a non-dihydrate azithromycin form conversion stabilizing excipient, and an azithromycin form conversion enhancer as recited in amended claim 1 of the subject application. Therefore, Applicants respectfully submit that claim 1 and claims 7-10, 16-20, 23 and 26 which depend directly or indirectly upon amended claim 1 are not anticipated by Curatolo, and request that the rejection of claims 1, 7-10, 16-20, 23 and 26 under 35 U.S.C § 102(b) be withdrawn.

IV. Rejection of Claims 1, 7-10, 16-21, 23 and 24 under 35 U.S.C. § 102(e)

Claims 1, 7-10, 16-21, 23 and 24 have been rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by U.S. Patent No. 6,764,997 to Tenengauzer et al. ("Tenengauzer") for the reasons set forth in the office action. Applicants respectfully traverse.

Tenengauzer relates to stabilized azithromycin dosage forms including a powder for oral suspensions. Tenengauzer states that his powder "may also contain conventional optional ingredients such as "wetting agents, anti-foaming agents, sweeteners and fillers, buffering agents, and preservatives (see col. 6, lines 54-63 of Tenengauzer). However, Tenengauzer does not disclose any powders for oral suspension comprising an azithromycin form conversion enhancer, let alone an oral suspension comprising a non-dihydrate azithromycin, a non-dihydrate azithromycin form conversion stabilizing excipient, and an azithromycin form conversion enhancer as recited in amended claim 1 of the subject application. Therefore, amended claim 1 of the subject application is

not anticipated by Tenengauzer, because Tenengauzer does not disclose every limitation of claim 1 as required by *Verdegaal Bros.* Thus, Applicants respectfully submit that claim 1 and claims 7-10, 16-21, 23 and 24 which depend directly or indirectly upon amended claim 1 are not anticipated by Tenengauzer, and request that the rejection of claims 1, 7-10, 16-21, 23 and 24 under 35 U.S.C. § 102(e) be withdrawn.

V. Rejection of Claims 11, 20-25 and 27-28 under 35 U.S.C. § 103(a)

1. Rejection of Claims 20-21 and 23-24 under 35 U.S.C. § 103(a)

The Examiner has rejected claims 20-21 and 23-24 under 35 U.S.C. 103(a) as allegedly being obvious over Curatolo in view of either Tenengauzer or U.S. Patent No. 6,977,243 to Li et al. ("Li") for the reasons set forth in the office action. Applicants respectfully traverse.

As noted above, neither Curatolo nor Tenengauzer disclose any formulation comprising an azithromycin form conversion enhancer as recited in amended claim 1. Moreover, neither Curatolo nor Tenengauzer teaches or even suggests making or using a powder containing an azithromycin form conversion enhancer. This deficiency of Curatolo and Tenengauzer is not overcome further in view of Li.

Li relates to crystal forms of azithromycin. Li describes a number of routes of administration of his crystal forms, one of which is "oral suspension" (see col. 26, lines 24-37). However, Li does not teach or suggest a powder for oral suspension comprising an azithromycin form conversion enhancer as recited in amended claim 1 of the subject application.

"To establish prima facie obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art." MPEP 2143.03 (citing *In re Royka*, 490 F.2d 981, 180 (CCPA 1974)).

For the reasons set forth above, the combination of Curatolo further in view of Tenengauzer or Li does not teach or suggest a powder for an oral suspension comprising an azithromycin form conversion enhancer as recited in amended claim 1 of the subject application. Thus, claims 20-21 and 23-24, which depend directly or indirectly upon amended claim 1, are not obvious over Curatolo in view of either Tenengauzer or Li for at least this reason.

In view of the above, Applicants respectfully submit that claims 20, 21, 23 and 24 are not obvious over Curatolo in view of either Tenengauzer or Li, and request that the rejection of claims 20, 21, 23 and 24 under 35 U.S.C. § 103(a) be withdrawn.

2. Rejection of Claims 21 and 22 under 35 U.S.C. § 103(a)

The Examiner has rejected claims 21 and 22 under 35 U.S.C. 103(a) as allegedly being obvious over Curatolo in view of either Tenengauzer or Li as applied to claim 20, and further in view of WO 2004/000865 ("Schwarz") for the reasons set forth in the office action. Applicants respectfully traverse.

Claims 21 and 22 depend directly or indirectly upon amended claim 1. As noted above, the combination of Curatolo further in view of Tenengauzer or Li does not teach or suggest any powder formulation comprising an azithromycin form conversion enhancer as recited in amended claim 1.

This deficiency of Curatolo further in view of Tenengauzer or Li is not overcome further in view of Schwarz.

Schwarz is directed to a monohydrate form of azithromycin and describes a composition for oral administration consisting of azithromycin monohydrate, a sweetener, a flavourant, a buffer, optionally a filler, and optionally a thickener (see page 1, lines 11-18 of Schwarz). However, Schwarz does not teach or suggest a powder for oral suspension comprising an azithromycin form conversion enhancer as recited in amended claim 1 of the subject application. Therefore, the combination of Curatolo further in view of Tenengauzer or Li, and further in view of Schwarz does not teach or suggest a powder for an oral suspension comprising an azithromycin form conversion enhancer as recited in amended claim 1 of the subject application. Thus, claims 21 and 22 which depend directly or indirectly upon amended claim 1 are not obvious over Curatolo in view of either Tenengauzer or Li, and further in view of Schwarz for at least this reason.

In view of the above, Applicants respectfully submit that claims 21 and 22 are not obvious over Curatolo in view of either Tenengauzer or Li, and further in view of Schwarz, and request that the rejection of claims 21 and 22 under 35 U.S.C. § 103(a) be withdrawn.

3. Rejection of Claims 24 and 25 under 35 U.S.C. § 103(a)

The Examiner has rejected claims 24 and 25 under 35 U.S.C. 103(a) as allegedly being obvious over Curatolo in view of U.S. Patent No. 6,365,574 to Singer et al. ("Singer") as applied to claim 23, and further in view of Schwarz for the reasons set forth in the office action. Applicants respectfully traverse.

As noted above, the combination of Curatolo and Schwarz does not teach or suggest a powder for oral suspension comprising an azithromycin form conversion enhancer as recited in amended claim 1 of the subject application. This deficiency of the combination of Curatolo and Schwarz is not overcome further in view of Singer.

Singer relates to an ethanolate of azithromycin and describes various compositions including powders for reconstitution (see col. 3, lines 24-27 of Singer). However, Singer does not teach or suggest a powder for oral suspension comprising an azithromycin form conversion enhancer as recited in amended claim 1 of the subject application. Therefore, the combination of Curatolo in view of Singer and further in view of Schwarz does not teach or suggest a powder for an oral suspension comprising an azithromycin form conversion enhancer as recited in amended claim 1 of the subject application. Thus, claims 24 and 25 which depend directly or indirectly upon amended claim 1 are not obvious over Curatolo in view of Singer and further in view of Schwarz for at least this reason.

In view of the above, Applicants respectfully submit that claims 24 and 25 are not obvious over Curatolo in view of Singer and further in view of Schwarz, and request that the rejection of claims 24 and 25 under 35 U.S.C. § 103(a) be withdrawn.

4. Rejection of Claims 27 and 28 under 35 U.S.C. § 103(a)

The Examiner has rejected claims 27 and 28 under 35 U.S.C. 103(a) as allegedly being obvious over Curatolo in view of U.S. Patent No. 6,245,903 to Karimian et al. ("Karimian") as applied

to claim 26, and further in view of Schwarz for the reasons set forth in the office action. Applicants respectfully traverse.

As noted above, the combination of Curatolo and Schwarz does not teach or suggest a powder for oral suspension comprising an azithromycin form conversion enhancer as recited in amended claim 1 of the subject application. This deficiency of the combination of Curatolo and Schwarz is not overcome further in view of Karimian.

Karimian relates to azithromycin monohydrate isopropanol clathrate. Karimian states that the azithromycin monohydrate isopropanol clathrate is not hydroscopic and "may be used in certain formulations of the drug product as tablet or capsule with excellent stability results" (see col. 3, lines 26-30 of Karimian). However, Karimian does not teach or suggest a powder for oral suspension comprising an azithromycin form conversion enhancer as recited in amended claim 1 of the subject application. Therefore, the combination of Curatolo in view of Karimian and further in view of Schwarz does not teach or suggest a powder for an oral suspension comprising an azithromycin form conversion enhancer as recited in amended claim 1 of the subject application. Thus, claims 27 and 28 which depend directly or indirectly upon amended claim 1 are not obvious over Curatolo in view of Karimian and further in view of Schwarz for at least this reason.

In view of the above, Applicants respectfully submit that claims 27 and 28 are not obvious over Curatolo in view of Karimian and further in view of Schwarz, and request that the rejection of claims 27 and 28 under 35 U.S.C § 103(a) be withdrawn.

5. Rejection of Claim 11 under 35 U.S.C. § 103(a)

The Examiner has rejected claim 11 under 35 U.S.C. 103(a) as allegedly being obvious over Curatolo in view of U.S. Patent No. 6,383,527 to Artman et al. ("Artman") for the reasons set forth in the office action. Applicants respectfully traverse.

As noted above, Curatolo does not teach or suggest a powder for oral suspension comprising an azithromycin form conversion enhancer as recited in amended claim 1 of the subject application. This deficiency of Curatolo is not overcome further in view of Karimian.

Artman relates to combinations of valerian extract and at least on NSAID and states that isoamyl isovalerate is an acceptable flavoring agent (see col. 8, line 7 of Artman). However, Artman does not teach or suggest a powder for oral suspension comprising an azithromycin form conversion enhancer as recited in amended claim 1 of the subject application. Therefore, the combination of Curatolo in view of Artman does not teach or suggest a powder for an oral suspension comprising an azithromycin form conversion enhancer as recited in amended claim 1 of the subject application. Thus, claim 11 which depends directly upon amended claim 1 is not obvious over Curatolo in view of Artman for at least this reason.

In view of the above, Applicants respectfully submit that claim 11 is not obvious over Curatolo in view of Artman, and request that the rejection of claim 11 under 35 U.S.C § 103(a) be withdrawn.

In summary, amended claim 1 and claims 11, 20-25 and 27-28 which depend directly or indirectly upon amended claim 1 are not obvious over Curatolo, Tenengauzer, Li, Schwarz, Singer,

Karimian and Artman, either alone or in combination, because that combination of references does not teach or suggest a form stabilization of a non-dihydrate azithromycin as recited in amended claim 1. Therefore, claims 1, 11, 20-25 and 27-28 are not obvious over Curatolo, Tenengauzer, Li, Schwarz, Singer, Karimian and Artman, either alone or in any combination. Thus, the rejection of claims 1, 11, 20-25 and 27-28 under 35 U.S.C § 103(a) must be withdrawn.

CONCLUSION

Applicants respectfully request prompt consideration of the pending claims and early allowance of the application. No additional fee is believed due. However, if any fee is due, the Examiner is authorized to charge the fee to Applicants' Deposit Account No. 16-1445.

If the Examiner wishes to comment or discuss any aspect of this application or response, Applicants' undersigned attorney invites the Examiner to call him at the telephone number provided below.

Respectfully submitted,

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